



03-07-06

1FW/B

PTO/SB/17 (12-04v2)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).		Complete if Known	
FEE TRANSMITTAL For FY 2005		Application Number	10/804,679
		Filing Date	March 18, 2004
		First Named Inventor	Andrew D. SUTTON
		Examiner Name	G. M. Konata
		Art Unit	1616
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Attorney Docket No.	263742002802
TOTAL AMOUNT OF PAYMENT		(\$)	180.00

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 03-1952 Deposit Account Name: Morrison & Foerster LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
10	- 20 = 0	x 50 =	0.00

Multiple Dependent Claims

<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
180	0.00

<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
1	- 3 = 0	x 200 =	0.00

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
	- 100 =	/50	(round up to a whole number) x	

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement 180.00

SUBMITTED BY			
Signature	<u>Shantanu Basu</u>	Registration No. (Attorney/Agent)	43,318
Name (Print/Type)	Shantanu Basu	Telephone	(650) 813-5995
		Date	March 3, 2006



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/804,679
	Filing Date	March 18, 2004
	First Named Inventor	Andrew D. SUTTON
	Art Unit	1616
	Examiner Name	G. M. Konata
Total Number of Pages in This Submission	12+51 References	Attorney Docket Number 263742002802

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form + duplicate (2 pages) <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement (3 pages) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): PTO/SB/08a/b + copy (6 pages) References (51) Return Receipt Postcard
<div>Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	MORRISON & FOERSTER LLP (Customer No. 25226)		
Signature			
Printed name	Shantanu Basu		
Date	March 3, 2006	Reg. No.	43,318

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 456357593 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.	
Dated: March 3, 2006	Signature: (Arlette Malhas)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 456357593, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: March 3, 2006

Signature: Arlette Malhas

(Arlette Malhas)

PATENT
Docket No. 263742002802

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Andrew D. SUTTON et al.

Serial No.: 10/804,679

Filing Date: March 18, 2004

For: SPRAY-DRIED MICROPARTICLES
AND THEIR USE AS THERAPEUTIC
VEHICLES

Examiner: G.M. Konata

Group Art Unit: 1616

Confirmation Code No. 8165

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

; 03/03/2006 AKLECH1 00000055 031952 10804679
01 FC:1806 180.00 DA

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.

- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
- ☐ A fee is required. A check in the amount of ___ is enclosed.
- ☒ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of ___ is enclosed.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other

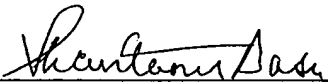
Application Serial No. 10/804,679

PATENT
Docket No. 263742002802

fees due in connection with the filing of this document to **Deposit Account No. 03-1952**
referencing 263742002802.

Dated: March 3, 2006

Respectfully submitted,

By 

Shantanu Basu

Registration No.: 43,318

MORRISON & FOERSTER LLP

755 Page Mill Road

Palo Alto, California 94304-1018

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ALTERNATIVE TO PTO/SB/08a/b (07-05)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/804,679
				Filing Date	March 18, 2004
				First Named Inventor	Andrew D. SUTTON
				Art Unit	1616
				Examiner Name	G.M. Konata
Sheet	1	of	3	Attorney Docket Number	263742002802
				Confirmation Number	8165

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-3,937,668-A	02-10-1976	Zolle	
	2.	US-4,830,858-A	05-16-1989	Payne et al.	
	3.	US-4,895,719-A	01-23-1990	Radhakrishnan et al.	
	4.	US-4,952,402-A	08-28-1990	Sparks et al.	
	5.	US-5,006,343-A	04-09-1991	Benson et al.	
	6.	US-5,011,678-A	04-30-1991	Wang et al.	
	7.	US-5,049,389-A	09-17-1991	Radhakrishnan	
	8.	US-5,098,893-A	03-24-1992	Franks et al.	
	9.	US-5,113,855-A	05-19-1992	Newhouse	
	10.	US-5,225,183-A	07-06-1993	Purewal et al.	
	11.	US-5,230,884-A	07-27-1993	Evans et al.	
	12.	US-5,254,330-A	10-19-1993	Ganderton et al.	
	13.	US-5,354,562-A	10-11-1994	Platz et al.	
	14.	US-5,458,135-A	10-17-1995	Patton et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	15.	DE-1080265	04-21-1960	Farbenfabriken Bayer Aktiengesellschaft		
	16.	EP-0 072 046-A1	02-16-1983	Fisons plc.		
	17.	EP-0257915-A1	03-02-1988	Innovata Biomed, Ltd.		
	18.	EP-0407028-A2	01-09-1991	Fisons PLC		
	19.	EP-0582459-B1	02-09-1994	Takeda Chemical Industries, Ltd.		
	20.	EP-0655237-A1	05-31-1995	Hoeschst Aktiengesellschaft		
	21.	EP-0748213-B1	12-18-1996	Nektar Therapeutics		
	22.	EP-0773781-B1	05-21-1997	Elan Drug Delivery, Ltd.		
	23.	GB-1122284-A	08-07-1968	Altounyan et al.		
	24.	GB-1182779-A	03-04-1970	Altounyan et al.		
	25.	JP-06-100464-A	04-12-1994	Asahi Chem Ind Co Ltd.	Machine Translation	
	26.	JP-52-139789-A	11-21-1977	Microbial Chem Res Found	Abstract	
	27.	SE-9302198	06-24-1993	Astra AB		
	28.	SE-9400370	02-04-1994	Astra AB		
	29.	WO-88/08298-A1	11-03-1988	Fuisz, Richard C.		
	30.	WO-90/11756-A1	10-18-1990	Aberdeen University		
	31.	WO-90/13285-A1	11-15-1990	Enzytech, Inc.		
	32.	WO-90/13328-A1	11-15-1990	Riker Laboratories, Inc.		
	33.	WO-91/16882-A1	11-14-1991	Liposome Technology, Inc.		

Examiner Signature		Date Considered	
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pa-1050123 v2

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/804,679
				Filing Date	March 18, 2004
				First Named Inventor	Andrew D. SUTTON
				Art Unit	1616
				Examiner Name	G.M. Konata
Sheet	3	of	3	Attorney Docket Number	263742002802
				Confirmation Number	8165

58.	Lee, S. et al. (April 1976). "Development of an Aerosol Dosage Form Containing Insulin," <i>Journal of Pharmaceutical Sciences</i> 65(4):567-572.	
59.	Levine, H. et al. (May 1992). "Another View of Trehalose for Drying and Stabilizing Biological Materials," <i>Biopharm</i> 5:36-40.	
60.	Mumenthaler, M. et al. (1994). "Feasibility Study on Spray-Drying Protein Pharmaceuticals: Recombinant Human Growth Hormone and Tissue-Type Plasminogen Activator," <i>Clinical Research</i> 11(1):12-20.	
61.	Priority document for EP0655237, German application no. DE-19934340434 filed on November 27, 1993, 9 pages.	
62.	Schluter, K.J. et al. (1984). "Pulmonary Administration of Human Insulin in Volunteers and Type I-Diabetics," <i>Diabetes</i> 33(Suppl.) page 75A: Abstract no. 298.	
63.	Vidgren, M. et al. (1988). "In Vitro and In Vivo Deposition of Drug Particles Inhaled From Pressurized Aerosol and Dry Powder Inhaler," Marcel Dekker, Inc., pages 2649-2665.	
64.	Wigley, F. M. et al. (1971). "Insulin Across Respiratory Mucosae by Aerosol Delivery," <i>Diabetes</i> 20(8):552-556.	
65.	Yoshida, H. et al. (May 1979). "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form," <i>Journal of Pharmaceutical Sciences</i> 68(5):670-671.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/804,679
				Filing Date	March 18, 2004
				First Named Inventor	Andrew D. SUTTON
				Art Unit	1616
				Examiner Name	G.M. Konata
Sheet	2	of	3	Attorney Docket Number	263742002802
				Confirmation Number	8165

	34.	WO-91/18091-A1	11-28-1991	Quadrant Holdings Cambridge Limited		
	35.	WO-93/00951-A1	01-21-1993	Inhale, Inc.		
	36.	WO-93/10758-A1	06-10-1993	Pitman-Moore, Inc.		
	37.	WO-93/11746-A1	06-24-1993	Boehringer Ingelheim International GMBH	Abstract	
	38.	WO-93/13752-A1	07-22-1993	SRI International		
	39.	WO-93/17663-A1	09-16-1993	Fisons PLC		
	40.	WO-93/23065-A1	11-25-1993	Applied Research Systems ARS Holding		
	41.	WO-94/00291-A1	01-06-1994	Fisons PLC		
	42.	WO-94/07514-A1	04-14-1994	Inhale Therapeutic Systems		
	43.	WO-94/13271-A1	06-23-1994	Aktiebolaget Astra		
	44.	WO-94-16717-A1	08-04-1994	Miris Medical Corporation		
	45.	WO-94/22423-A1	10-13-1994	Bukh Meditec A/S		
	46.	WO-95/00127-A1	01-05-1995	Astra Aktiebolag		
	47.	WO-95/00128-A1	01-05-1995	Astra Aktiebolag		
	48.	WO-95/01324-A1	01-12-1995	Glaxo Group Limited		
	49.	WO-95/11666-A1	05-04-1995	Coordinated Drug Development Ltd.		
	50.	WO-95/24183-A1	09-14-1995	Inhale Therapeutic Systems		
	51.	WO-95/31479-A1	11-23-1995	Inhale Therapeutic Systems, Inc.		

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	52.	Broadhead, J. et al. (1992). "The Spray Drying of Pharmaceuticals," <i>Drug Development and Industrial Pharmacy</i> 18(11&12):1169-1206.			
	53.	Broadhead, J. et al. (June 1994). "The Effect of Process and Formulation Variable on the Properties of Spray-Dried β -Galactosidase," <i>J. Pharm. Pharmacol.</i> 46(6):458-467.			
	54.	Graham, D. T. et al. (1984). "An In-Vitro Test for the Duration of Insulin Suspension," <i>J. Pharm. Pharmacol.</i> 36(7):427-430.			
	55.	Hahn, L. et al. (1989) "Solid Surfactant Solutions Of Active Ingredients In Sugar Esters," <i>Pharmaceutical Research</i> 6(11):958-960.			
	56.	Heubner, W. et al. (1924). "Kurze Wissenschaftliche Mitteilungen Uber Inhalation Von Insulin," <i>Klin Wochenschrift</i> 51:2342-2343.			
	57.	Köhler, D. (1990). "Aerosols for Systemic Treatment," <i>Lung. (Suppl.)</i> :677-684.			

Examiner Signature		Date Considered	
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